

HFA 305

Approval letter dated: NOV - 8 2002

FREEDOM OF INFORMATION SUMMARY

**SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG
APPLICATION**

ANADA 200-075

Sacox®

"Addition of Roaster, Replacement (Breeder and Layer) Chickens and Quail"

Sponsored by:
Intervet Inc.
Millsboro, DE 19966

ANADA 200-075

FOIS-1

FREEDOM OF INFORMATION SUMMARY

ANADA 200-075

I. GENERAL INFORMATION

ANADA Number: 200-075

Sponsor: Intervet Inc.
405 State Street
Millsboro, DE 19966-0318

Generic Names: salinomycin sodium

Trade Name: Sacox®

Effect of Supplement: To add roaster and replacement (breeder and layer) chickens to the label claim for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*; and to add quail to the label claim for the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*.

How Dispensed: OTC

Amount of Active Ingredient: Type A Medicated Article containing 60 grams salinomycin sodium per pound.

Pioneer Product: Bio-Cox®; salinomycin sodium; NADA #128-686; Alpha, Inc.

II. INDICATIONS FOR USE

BROILER, ROASTER, REPLACEMENT (BREEDER AND LAYER) CHICKENS

For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

QUAIL

For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*.

III. DOSAGE

- | | |
|---|--|
| A. DOSAGE FORM | Type A medicated article to be mixed with feed to produce a Type C medicated feed. |
| B. ROUTE OF ADMINISTRATION | This drug is administered orally by adding Type A medicated article to feed to make complete feed (Type C medicated feed). |
| C. RECOMMENDED DOSAGES: | |
| BROILER, ROASTER, REPLACEMENT
(BREEDER AND LAYER) CHICKENS | 40 to 60 g/ton of Type C medicated feed |
| QUAIL | 50 g/ton of Type C medicated feed |

IV. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1998, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter, Bioequivalence Guidance, October 10, 2000).

Based upon the formulation characteristics of the generic product, Sacox®, was granted a waiver dated December 28, 1992, from conducting an *in vivo* bioequivalency study. The abbreviated new animal drug application was approved on February 23, 1994. The generic and pioneer products contain the same active but different inactive ingredients and are medicated feed products.

V. HUMAN FOOD SAFETY

a. Acceptable Daily Intake (ADI)

The ADI for total residues of salinomycin is 0.005 milligram per kilogram of body weight per day.

b. Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal period assigned to the generic product is the same as that previously assigned to the pioneer product. A zero withdrawal is established for salinomycin sodium in roaster chicken, replacement (breeder and layer) chicken and quail feed.

c. Regulatory Method

A regulatory method was not required.

VI. AGENCY CONCLUSIONS

This Supplemental Abbreviated New Animal Drug Application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrated that Sacox® is safe and effective for its labeled indications, when used under its proposed conditions of use.

VII. ATTACHMENTS

The following generic labeling and currently approved pioneer labeling are available.

1. Package label for generic Type A medicated article – Sacox
2. Package bluebird labels for generic Type C medicated feed (chicken and quail).
3. Pioneer package label for Type A medicated article – Biocox
4. Pioneer blue bird laels for Type C medicated feed (chicken and quail).

Copies of these labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1746. If there are problems sending a fax, call (301) 827-6567.

(Side Panel)

intervet

(Front Panel)

(Side Panel)

Sacox[®] 60

**Brand of salinomycin sodium
Type A Medicated Article**

Sacox[®] 60

Active Drug Ingredient:

Salinomycin equivalent to 60 grams salinomycin sodium activity per pound.

Other Ingredients:

Calcium Carbonate, Mineral Oil, Calcium Silicate and Silicon Dioxide.

Important: See back panel for use directions.

Net Weight 50 LB (22.68 kg)

intervet

Sacox[®] 60

intervet

(Back Panel)

Sacox® 60

**Brand of salinomycin sodium
Type A Medicated Article**

**For use in broiler, roaster, replacement
(breeder and layer) chickens and quail only**

Active drug ingredient	Salinomycin equivalent to 60 grams salinomycin sodium activity per pound																									
For use in manufacturing medicated feeds only																										
Broiler, roaster and replacement (breeder and layer) chickens	Use Sacox® 60 to provide salinomycin sodium concentrations ranging from 40-60 g/ton (0.0044% to 0.0066%) for the prevention of coccidiosis in broiler, roaster and replacement chickens caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> and <i>E. mivati</i> . The dosage should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions.																									
Quail	Use Sacox® 60 to provide salinomycin sodium concentrations of 50 g/ton (0.0055%) for the prevention of coccidiosis in quail caused by <i>Eimeria dispersa</i> and <i>E. lettyae</i> .																									
Mixing Directions	<div>Thoroughly mix Sacox® 60 with non-medicated feed to provide the level of salinomycin sodium per ton as indicated in the table below.</div> <table><tr><th rowspan="2">Salinomycin Sodium Activity</th><th colspan="2">Amount of Sacox 60 Type A Medicated Article (60 g/lb) Per Ton of Feed</th></tr><tr><th>Lbs</th><th>Grams</th></tr><tr><td>(grams per ton)</td><td></td><td></td></tr><tr><td>40</td><td>0.67</td><td>304</td></tr><tr><td>45</td><td>0.75</td><td>341</td></tr><tr><td>50</td><td>0.83</td><td>377</td></tr><tr><td>55</td><td>0.92</td><td>418</td></tr><tr><td>60</td><td>1.00</td><td>454</td></tr></table>			Salinomycin Sodium Activity	Amount of Sacox 60 Type A Medicated Article (60 g/lb) Per Ton of Feed		Lbs	Grams	(grams per ton)			40	0.67	304	45	0.75	341	50	0.83	377	55	0.92	418	60	1.00	454
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Feeding Directions	Feed continuously as the only ration.																									
Important	Must be thoroughly mixed in feeds before use. Not approved for use with pellet binders.																									
Caution	No withdrawal required. May be fatal if accidentally fed to adult turkeys or to horses.																									
<div>➡</div> Warning	Do not feed to laying hens producing eggs for human consumption. When mixing and handling Sacox® 60 premix, use protective clothing, impervious gloves, eye protection and an approved dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water. <div>⬅</div>																									
	<div>• Store in a cool, dry place.</div> <div>ANADA # 200-075, Approved by FDA</div>																									
Distributed by: Intervet Inc. Millsboro, DE <div>Intervet</div>	<div>[BAR CODE GOES HERE]</div> <div>Net wt 50 LB (22.68 kg)</div>																									

NET WEIGHT ON BAG OR INVOICE

Salinomycin Quail Feed**TYPE C MEDICATED FEED****INDICATIONS:**

For the prevention of coccidiosis in quail caused by *Eimeria dispersa* and *E. lettyae*.

ACTIVE DRUG INGREDIENT

Salinomycin sodium 50 grams per ton (0.0055%)

GUARANTEED ANALYSIS

Crude Protein, not less than	___%
Lysine, not less than	___%
Methionine, not less than	___%
Crude Fat, not less than	___%
Crude Fiber, not more than	___%
Calcium, not less than	___%
Calcium, not more than	___%
Phosphorous, not less than	___%
Salt ¹ , not less than	___%
Salt ¹ , not more than	___%
Sodium ² , not less than	___%
Sodium ² , not more than	___%

¹ If added.

² Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed continuously as the sole ration. Not approved for use with pellet binders.

**CAUTION: MAY BE FATAL IF ACCIDENTALLY FED TO ADULT TURKEYS
OR TO HORSES.**

**WARNING: DO NOT FEED TO LAYING HENS PRODUCING EGGS FOR
HUMAN CONSUMPTION.**

Lot No.

**MANUFACTURED BY
BLUE BIRD FEED MILLS
Robin, Indiana**

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NET WEIGHT ON BAG OR INVOICE

**Salinomycin Broiler, Roaster, and Replacement (Breeder and Layer)
Chicken Feed****TYPE C MEDICATED FEED****INDICATIONS:**

For the prevention of coccidiosis in broiler, roaster and replacement (breeder and layer) chickens caused by *Eimeria tenella*, *E. nectarix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*.

ACTIVE DRUG INGREDIENT

Salinomycin sodium 40 – 60 grams per ton (0.0044 – 0.0066%)

GUARANTEED ANALYSIS

Crude Protein, not less than	___%
Lysine, not less than	___%
Methionine, not less than	___%
Crude Fat, not less than	___%
Crude Fiber, not more than	___%
Calcium, not less than	___%
Calcium, not more than	___%
Phosphorous, not less than	___%
Salt ¹ , not less than	___%
Salt ¹ , not more than	___%
Sodium ² , not less than	___%
Sodium ² , not more than	___%

¹ If added.

² Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed continuously as the sole ration. Not approved for use with pellet binders.

**CAUTION: MAY BE FATAL IF ACCIDENTALLY FED TO ADULT TURKEYS
OR TO HORSES.**

**WARNING: DO NOT FEED TO LAYING HENS PRODUCING EGGS FOR
HUMAN CONSUMPTION.**

Lot No.

**MANUFACTURED BY
BLUE BIRD FEED MILLS
Robin, Indiana**

ALPHARMA
Pharmaceutical Division

Bio-Cox®

Granular 60

Bio-Cox
Granular 60

Granular 60

Bio-Cox

ALPHARMA
Pharmaceutical Division

Brand of salicylic acid sodium
Special Medication
Net Wt. 305.1g (12.631g)

ALPHARMA
Pharmaceutical Division

Bio-Cox

Granular 60

Brand of salinomycin sodium Type A Medicated Article

For use in broiler, roaster, replacement
(breeder and layer) chickens and quail only

**Active drug
ingredient**

Salinomycin equivalent to 60 grams salinomycin sodium activity per pound

For use in manufacturing medicated feeds only
**Broiler,
roaster and
replacement
(breeder
and layer)
chickens**

Use Bio-Cox 60 Granular to provide salinomycin sodium concentrations ranging from 40-60 g/ton (0.0044% to 0.0066%) for the prevention of coccidiosis in broiler, roaster and replacement chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mitis*. The dosage should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions.

Quail

Use Bio-Cox 60 Granular to provide salinomycin sodium concentrations of 50 g/ton (0.0055%) for the prevention of coccidiosis in quail caused by *Eimeria dispersa* and *E. lettyae*.

**Mixing
directions**

Thoroughly mix Bio-Cox 60 Granular with non-medicated feed to provide the level of salinomycin sodium per ton as indicated in the table below.

Salinomycin Sodium Activity (grams per ton)	Amount of Bio-Cox 60 Granular Type A Medicated Article (60 g/lb) Per Ton of Feed	
	lb	grams
40	0.67	304
45	0.75	341
50	0.83	377
55	0.92	418
60	1.00	454

**Feeding
directions**

Feed continuously as the sole ration

Important

Must be thoroughly mixed in feeds before use. Not approved for use with pellet binders.

Caution

May be fatal if fed to adult turkeys or to horses.

Warning

Do not feed to laying hens producing eggs for human consumption. When mixing and handling Bio-Cox 60 Granular premix, use protective clothing, impervious gloves, eye protection, and an approved dust respirator. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

Store in a cool, dry place

NADA #128-686, Approved by FDA

Marketed by

 **ALPHARMA**
Animal Health Division

Alpha Inc.
One Executive Drive
Fort Lee, New Jersey 07024

Take Time



Observe Label
Directions

Net wt 50 LB (22.68 kg)

Made in USA

AHG-029 0103

NET WEIGHT ON BAG OR INVOICE

**Salinomycin Broiler, Roaster, and Replacement (Breeder and Layer)
Chicken Feed**

TYPE C MEDICATED FEED

INDICATIONS:

For the prevention of coccidiosis in broiler, roaster and replacement (breeder and layer) chickens caused by *Eimeria tenella*, *E. nectarix*, *E. acervulina*, *E. maxima*, *E. brunetti* and *E. mivati*.

ACTIVE DRUG INGREDIENT

Salinomycin sodium 40 – 60 grams per ton (0.0044 – 0.0066%)

GUARANTEED ANALYSIS

Crude Protein, not less than	___%
Lysine, not less than	___%
Methionine, not less than	___%
Crude Fat, not less than	___%
Crude Fiber, not more than	___%
Calcium, not less than	___%
Calcium, not more than	___%
Phosphorous, not less than	___%
Salt ¹ , not less than	___%
Salt ¹ , not more than	___%
Sodium ² , not less than	___%
Sodium ² , not more than	___%

¹ If added.

² Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed continuously as the sole ration. Not approved for use with pellet binders.

**CAUTION: MAY BE FATAL IF ACCIDENTALLY FED TO ADULT TURKEYS
OR TO HORSES.**

**WARNING: DO NOT FEED TO LAYING HENS PRODUCING EGGS FOR
HUMAN CONSUMPTION.**

Lot No.

**MANUFACTURED BY
BLUE BIRD FEED MILLS
Robin, Indiana**

NET WEIGHT ON BAG OR INVOICE

Salinomycin Quail Feed

TYPE C MEDICATED FEED

INDICATIONS:

For the prevention of coccidiosis in quail caused by *Eimeria dispersa* and *E. lettyae*.

ACTIVE DRUG INGREDIENT

Salinomycin sodium 50 grams per ton (0.0055%)

GUARANTEED ANALYSIS

Crude Protein, not less than	___%
Lysine, not less than	___%
Methionine, not less than	___%
Crude Fat, not less than	___%
Crude Fiber, not more than	___%
Calcium, not less than	___%
Calcium, not more than	___%
Phosphorous, not less than	___%
Salt ¹ , not less than	___%
Salt ¹ , not more than	___%
Sodium ² , not less than	___%
Sodium ² , not more than	___%

¹ If added.

² Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

INGREDIENTS

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

FEEDING DIRECTIONS

Feed continuously as the sole ration. Not approved for use with pellet binders.

**CAUTION: MAY BE FATAL IF ACCIDENTALLY FED TO ADULT TURKEYS
OR TO HORSES.**

**WARNING: DO NOT FEED TO LAYING HENS PRODUCING EGGS FOR
HUMAN CONSUMPTION.**

Lot No.

**MANUFACTURED BY
BLUE BIRD FEED MILLS
Robin, Indiana**